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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/686,970	10/16/2003	Rudolf Pachl	5727-73662	8089

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BARNES & THORNBURG LLP  
11 SOUTH MERIDAN STREET  
INDIANAPOLIS, IN 46204

EXAMINER
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RAMILLANO, LORE JANET

ART UNIT	PAPER NUMBER
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1743

MAIL DATE	DELIVERY MODE
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06/04/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/686,970	<b>Applicant(s)</b> PACHL ET AL.	
	<b>Examiner</b> Lore Ramillano	<b>Art Unit</b> 1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 07 March 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 19 and 21-37 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 23-31 is/are allowed.
- 6) ☒ Claim(s) 19, 21, 22 and 32-37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>4/4/07</u> . | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

1. In applicant's reply filed on 3/7/07, applicant amended claims 19, 21, 28, and 29; and cancelled claim 20.

#### *Allowable Subject Matter*

2. The indicated allowability of claim 21 is withdrawn in view of the newly discovered reference to Moorman et al. ("Moorman"). Rejections based on the newly cited reference(s) follow.

#### *Prior art rejections*

3. The rejections over Charlton, Phillips '761, and Phillips '692 are withdrawn. New rejections follow.

#### *Claim Rejections - 35 USC § 102*

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. **Claims 21, 32, and 33** are rejected under 35 U.S.C. 102(b) as being anticipated by Moorman (US 5356782).

Moorman teaches a method comprising: a test field (10); a reagent in the test field (i.e. regions I, II, and III), wherein (i) the interaction between the reagent and the analyte causes a first photometrically detectable signal and (ii) the first photometrically detectable signal is a function of concentration of the analyte in the sample (i.e. column 8, lines 31-43); and a control substance in the test field, wherein (i) the interaction between the control substance and the sample matrix causes a second photometrically detectable signal and (ii) the second

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photometrically detectable signal is a function of the amount of the sample applied to the test field (i.e. column 8, lines 3-30). Moorman's signals are photometrically detectable because he teaches in column 17, lines 57-62, for example, that the interactions disclosed above were observed by fluorescence under long wave UV light.

Furthermore, Moorman teaches that the latter interaction stated above is a function of the amount of sample applied to the test field because he teaches in column 14, lines 47 to column 15, line 14, for example, that the test strips can be prepared to perform "concentration assay," which is an assay to determine whether an analyte of interest is present in excess of insufficiency in a sample.

6. **Claims 32, 33, and 35** are rejected under 35 U.S.C. 102(b) as being anticipated by Fleming et al. ("Fleming," US 6365417).

In figures 1-7, Fleming teaches a method comprising: a test field (i.e. 80 and 86); a reagent (i.e. capture agents) in the test field, wherein (i) the interaction between the reagent and the analyte causes a first photometrically detectable signal and (ii) the first photometrically detectable signal is a function of concentration of the analyte in the sample; and a control substance (i.e. fluorescein, 102, column 7, lines 7-8) in the test field, wherein (i) the interaction between the control substance and the sample matrix (i.e. saliva or other oral secretions collected) causes a second photometrically detectable signal and (ii) the second photometrically detectable signal is a function of the amount of the sample applied to the test field (i.e. column 9, line 35 to column 10, line 10). Fleming's signals are photometrically detectable because he teaches in column 6, line 64 to column 7, line 8, for example, that the interactions disclosed above were observed by visual, spectroscopic, photochemical, biochemical, immunochemical, electrical, optical or chemical means.

***Claim Rejections - 35 USC § 103***

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. **Claims 19, 22, and 38** are rejected under 35 U.S.C. 103(a) as being unpatentable over Moorman in view of Polito et al. ("Polito," US 6136610).

The teachings of Moorman are stated above. Moorman does not specifically teach correcting the analyte content of the sample if the amount of the sample placed on the test element is determined to be less than a predetermined calibration value. Polito teaches utilizing control agents that bind specifically to control binding agent to form a control binding pair, which represent internal controls. The purpose of having internal controls is to act as the standard to which the analyte measurement results may be compared. Thus, the effect of having these internal controls would compensate for variations pertaining to the test strip. (i.e. column 6, lines 32-49).

It would have been obvious to a person of ordinary skill in the art to modify Moorman's invention by incorporating the step of correcting the analyte content of the sample by utilizing internal controls because it would ensure that Moorman's test results are accurate and consistent despite having a varied amounts of sample placed, each time, on the test element.

9. **Claim 34** is rejected under 35 U.S.C. 103(a) as being unpatentable over Moorman in view of Carr et al. ("Carr," WO 01/25171 A1).

The teachings of Moorman are stated above. Moorman does not specifically teach having a control substance comprising a chromophore. Carr teaches utilizing a chromophore because it enables quantitation of the products of a synthesis to be carried out. Carr further teaches that such quantitation can be absolute quantitation or relative quantitation, or both. (i.e.

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p. 7, lines 23-30). It would have been obvious to a person of ordinary skill in the art to incorporate a chromophore into Moorman's invention because a chromophore has a very strong absorption at a unique or characteristic wavelength, which is usually distinct from the wavelengths at which the maximum absorbances of a typical substrate molecule might be found. (i.e. p. 7, lines 23-30).

10. **Claim 35** is rejected under 35 U.S.C. 103(a) as being unpatentable over Moorman in view of Caspers et al. ("Caspers," US 4081672).

The teachings of Moorman are stated above. Moorman does not specifically teach having a control substance comprising a fluorescein. Caspers teaches utilizing sodium fluorescein dye because it has the advantage that fluorescence may be detected in solution concentrations as small as  $1 \times 10^{-7}$  mole concentrations where at about 5200A the extinction coefficient is roughly  $0.01\text{cm}^{-1}$ . (i.e. column 3, lines 9-15). It would have been obvious to a person of ordinary skill in the art to modify Moorman by incorporating a fluorescein dye as a control substance since the amount of analyte that is collected in each sample is in minute amounts and incorporating a fluorescein dye would enable that analyte to be detectable.

11. **Claim 36** is rejected under 35 U.S.C. 103(a) as being unpatentable over Moorman in view of Mach et al. ("Mach," US 5723308).

The teachings of Moorman are stated above. Moorman does not specifically teach having a control substance comprising chlorophenol red. Mach teaches the benefit of using a large excess of chlorophenol red is the bright red color of chlorophenol red in contrast with the other colors in a solution allows easier and faster detection of the specimen (i.e. column 5, lines 38-50). It would have been obvious to a person of ordinary skill in the art to modify Moorman by incorporating chlorophenol red as the control substance because it would be desirable to use a

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control substance that produces a distinguishable color when it interacts with the sample to make it easier for the analyst to quickly determine the signal produced by the control substance.

12. **Claim 37** is rejected under 35 U.S.C. 103(a) as being unpatentable over Moorman in view of Mach, as applied to claim 36 above, and further in view of applicant's admitted prior art on page 15 of the specification.

The teachings of Moorman and Mach are stated above. Moorman in view of Mach does not specifically teach having a reagent comprising phosphomolybdic acid. However, applicant teaches that the use of 2, 18 phosphomolybdic acid in the detection of glucose is known in the art. It would have been obvious to a person of ordinary skill in the art to modify the modified Moorman by incorporating phosphomolybdic acid as a reagent for glucose because it would be desirable to utilize a reagent that is easily available and well-known to be used for such detection.

***Allowable Subject Matter***

13. Claims 23-31 are allowed.


The following is an examiner's statement of reasons for allowance: the prior art of record (Moorman) fails to teach or fairly suggest an electronic circuit or assembly operatively coupled to the optical measuring device, which is configured to analyze the first photometrically detectable signal from the optical measuring device to determine the analyte content of the sample based on the concentration of the analyte in the sample, and analyze the second photometrically detectable signal from the optical measuring device to determine whether an underdosage of the sample has occurred on the test element based on the interaction between the control substance and the sample matrix, in combination with the remaining features and elements of the claimed invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lore Ramillano whose telephone number is (571) 272-7420. The examiner can normally be reached on Mon. to Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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